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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ACTAVIS LLC; APOTEX, INC.; APOTEX, CORP.; GLAND PHARMA LTD.; DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES LTD.; EMCURE PHARMACEUTICALS USA, INC.; EMCURE PHARMACEUTICALS, LTD; HOSPIRA, INC.; PHARMACEUTICS INTERNATIONAL INC.; SAGENT PHARMACEUTICALS, INC.; ACS DOBFAR INFO S.A.; STRIDES, INC.; AGILA SPECIALTIES PRIVATE LTD.; SUN PHARMA GLOBAL FZE; CARACO PHARMACEUTICAL LABORATORIES, LTD; SUN PHARMACEUTICAL INDUSTRIES LTD.; WOCKHARDT USA LLC; and WOCKHARDT LTD. Defendants.	Civil Action No. 13-1028 (SDW) (MCA)

NOVARTIS'S ANSWER TO THE COUNTERCLAIMS OF HOSPIRA, INC.

Novartis Pharmaceuticals Corporation ("Novartis"), by and through its undersigned attorneys, under Fed. R. Civ. P. 12, hereby submits this Answer to the counterclaims of Hospira Inc. ("Hospira") to the Corrected Amended Complaint (D.I. 198, hereinafter "Counterclaims"). For the convenience of the Court, Novartis uses the section headings as posed by Hospira in the Counterclaims, and does not purport to concur with the conclusions made therein. Accordingly, this Answer responds to those allegations as follows:

THE PARTIES

1. Hospira is a corporation organized and existing under the laws of Delaware with its principal place of business at 275 N. Field Drive, Lake Forest, Illinois 60045.

Admitted on information and belief.

2. On information and belief, and according to its Amended Complaint filed in this action, Novartis is a corporation organized under Delaware law, with its principal place of business in East Hanover, New Jersey.

Admitted.

JURISDICTION AND VENUE

3. These counterclaims arise under the Patent Act of 1952, 35 U.S.C. §§ 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

Paragraph 3 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis admits that the Counterclaims purport to arise under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. Moreover, Novartis does not dispute that this Court has jurisdiction over the subject matter of this action.

4. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

Paragraph 4 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, for purposes of this action only, Novartis does not dispute that venue is proper in this judicial district.

BACKGROUND

5. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., as amended by the Hatch-Waxman Amendments, sets forth the rules that the U.S. Food & Drug Administration ("FDA") follows when considering the approval of applications for both brand-name and generic drugs.

Paragraph 5 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis refers to the full text of 21 U.S.C. §§ 301 *et seq*. for their contents.

6. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

Paragraph 6 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis refers to the full text of 21 U.S.C. § 355 for its contents.

7. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

Paragraph 7 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis refers to the full text of 21 U.S.C. § 355(b)(1) and (c)(2), as well as 21 C.F.R. §§ 314.53(b) and (c)(2), for their contents.

8. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

Paragraph 8 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis refers to the full text of 21 U.S.C. § 355(j)(7)(A)(iii) for its contents.

9. Generic drugs are versions of brand-name prescription drugs that have been shown to be "bioequivalent" to the listed reference NDA drug approved by the FDA. *See* 21 U.S.C. § 355(j)(4)(F). Under the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, *see* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e)), a generic manufacturer submits what is called an Abbreviated New Drug Application to obtain approval to sell a generic drug.

Paragraph 9 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis refers to the full text of 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e) for their contents.

10. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of the ANDA applicant's generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

Paragraph 10 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis refers to the full text of 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.94(a)(12) for their contents.

11. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product before patent expiration. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Paragraph 11 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis refers to the full text of 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for its contents.

12. Hospira filed ANDA No. 202837 with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of a generic pharmaceutical product, zoledronic acid, that is related to the zoledronic acid product that is the subject of NDA No. 021817. Novartis is identified in FDA records as the approval holder of NDA No. 021817.

Novartis admits that Novartis is identified in FDA records as the approval holder of NDA No. 021817. Novartis admits the remaining allegations of Paragraph 12 on information and belief.

13. Hospira's ANDA No. 202837 included a "Paragraph IV" certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) with respect to U.S. Patent Nos. 7,932,241 and 8,052,987. Hospira alleged that these patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the proposed zoledronic acid drug product described by Hospira's ANDA No. 202837.

Admitted on information and belief.

THE ’241 PATENT

14. The ’241 patent was issued on April 26, 2011, to Glausch, Löffler, and Sigg and assigned to Novartis AG. On information and belief, Novartis is the current owner of the ‘241 patent which is scheduled to expire no later than February 5, 2028.

Novartis admits that the ’241 patent was issued on April 26, 2011, to Glausch, Löffler, and Sigg and assigned to Novartis. Novartis further admits that Novartis is the current owner of the ’241 patent, which is scheduled to expire on February 5, 2028, with pediatric exclusivity until August 5, 2028.

15. Novartis listed the ’241 patent in the Orange Book in connection with Reclast and Zometa.

Novartis admits that the U.S. Food and Drug Administration’s official publication of approved drugs (the “Orange Book”) lists the ’241 patent in connection with RECLAST® and ZOMETA®. Novartis denies the remaining allegations in Paragraph 15.

16. To have the ’241 patent listed in the Orange Book, the law required Novartis to certify to the FDA, under oath, that the ’241 patent claims the “drug” zoledronic acid or a “method of using” zoledronic acid and is a patent for which a claim of patent infringement could reasonably be asserted against an authorized party.

Paragraph 16 of the Counterclaims states legal conclusions as to which no response is required.

17. By bringing suit against Hospira, Novartis has taken active steps to block and/or interfere with Hospira's attempt to launch a generic zoledronic acid drug product or products.

Novartis admits that it has filed suit against Hospira alleging infringement of the '241 and '987 patents and seeks remedy. Novartis denies the remaining allegations in Paragraph 17.

18. The claims of the '241 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Hospira's proposed zoledronic acid drug product(s).

Denied.

19. Because of the foregoing facts, there is a real, substantial, immediate, and continuing justiciable controversy between Hospira and Novartis as to liability for infringement of, and validity and/or enforceability of, the '241 patent.

Paragraph 19 of the Counterclaims states legal conclusions as to which no response is required. To the extent a response is required, Novartis admits that there exists a justiciable controversy between Novartis and Hospira regarding the infringement and validity of the '241 patent. Novartis denies the remaining allegations in Paragraph 19.

THE ’987 PATENT

20. The ’987 patent was issued on November 8, 2011, to Horowitz, Richardson, and Trechsel and assigned to Novartis Pharmaceuticals Corporation. On information and belief, Novartis is the current owner of the ’987 patent which is scheduled to expire no later than June 18, 2021.

Novartis admits that the ’987 patent was issued on November 8, 2011, to Horowitz, Richardson, and Trechsel and assigned to Novartis and that Novartis is the current owner of the ’987 patent, but denies the remaining allegations of Paragraph 20.

21. Novartis listed the ’987 patent in the Orange Book in connection with Reclast and Zometa.

Novartis admits that the U.S. Food and Drug Administration’s official publication of approved drugs (the “Orange Book”) lists the ’987 patent in connection with RECLAST®. Novartis denies the remaining allegations in Paragraph 21.

22. To have the ’987 patent listed in the Orange Book, the law required Novartis to certify to the FDA, under oath, that the ’987 patent claims the “drug” zoledronic acid or a “method of using” zoledronic acid and is a patent for which a claim of patent infringement could reasonably be asserted against an authorized party.

Paragraph 22 of the Counterclaims states legal conclusions as to which no response is required.

23. By bringing suit against Hospira, Novartis has taken active steps to block and/or interfere with Hospira's attempt to launch a generic zoledronic acid drug product or products.

Novartis admits that it has filed suit against Hospira alleging infringement of the '241 and '987 patents and seeks remedy. Novartis denies the remaining allegations in Paragraph 23.

24. The claims of the '987 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Hospira's proposed zoledronic acid drug product(s).

Denied.

25. Because of the foregoing facts, there is a real, substantial, immediate, and continuing justiciable controversy between Hospira and Novartis as to liability for infringement of, and validity and/or enforceability of, the '987 patent.

Paragraph 25 of the Counterclaims states a legal conclusion as to which no response is required. To the extent a response is required, Novartis admits that there exists a justiciable controversy between Novartis and Hospira regarding the infringement and validity of the '987 patent. Novartis denies the remaining allegations of Paragraph 25 of the Counterclaims.

COUNTERCLAIM I
(DECLARATION OF INVALIDITY OF THE '241 PATENT)

26. Hospira realleges and incorporates by reference the allegations contained in paragraphs 1-25 of the Counterclaims as if set forth here.

Novartis incorporates by reference each of its answers to Paragraphs 1-25 above as if fully set forth herein.

27. The claims of the '241 patent are invalid under the provisions of 35 U.S.C. § 102 and/or § 103 for at least the reasons stated in Hospira's Notice Letter dated May 26, 2011.

Denied.

28. Specifically, the claims of the '241 patent are invalid as anticipated and/or obvious over at least the following prior art references:

a. Canadian Patent Application Publication No. CA 2372450 A1;

b. Patent Cooperation Treaty Publication No. WO 02/22136;

c. the Zometa® Product Label;

d. the Blow-Fill-Seal Technology publication; and

e. the FDA Guideline on Sterile Drug Products Produced by Aseptic Processing.

Denied.

29. The claims of the ’241 patent are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full scope of the claimed invention and/or enabling a person having ordinary skill in the art to use the claimed invention.

Denied.

30. Hospira is entitled to a declaratory judgment that the claims of the ’241 patent are invalid.

Paragraph 30 of the Counterclaims states a legal conclusion as to which no response is required. To the extent a response is required, Novartis denies the allegation in Paragraph 30.

COUNTERCLAIM II
(DECLARATION OF INVALIDITY OF THE ’987 PATENT)

31. Hospira realleges and incorporates by reference the allegations contained in paragraphs 1-30 of the Counterclaims as if set forth here.

Novartis incorporates by reference each of its answers to Paragraphs 1-30 above as if fully set forth herein.

32. The claims of the ’987 patent are invalid under the provisions of 35 U.S.C. § 102 and/or § 103 for at least the reasons stated in Hospira’s Notice Letter dated December 6, 2011.

Denied.

33. Specifically, the claims of the '987 patent are invalid as anticipated and/or obvious over at least the following prior art references:

a. Patent Cooperation Treaty Publication No. WO 95/30421;

b. Heikkinen *et al.*, Short-term Intravenous Bisphosphonates in Prevention of Postmenopausal Bone Loss;

c. Green *et al.*, preclinical Pharmacology of CGP 42'446, a New, Potent, Heterocyclic Bisphosphonate Compound;

d. Boutsen, "Primary Prevention of Glucocorticoid-induced Osteoporosis with Intraveneous Pamidronate Given on 2 Different Regimens: a Prospective Controlled Study", *Bone* 23(5), S313 (1998); and

e. "*Update: Bisphosphonates*", *Lunar News*, Spring 1999, pages 27-29.

Denied.

34. The claims of the '987 patent are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full scope of the claimed invention and/or enabling a person having ordinary skill in the art to use the claimed invention.

Denied.

35. Hospira is entitled to a declaratory judgment that the claims of the '987 patent are invalid.

Paragraph 35 of the Counterclaims states a legal conclusion as to which no response is required. To the extent a response is required, Novartis denies the allegation in Paragraph 35.

COUNTERCLAIM III
(DECLARATION OF NON-INFRINGEMENT OF THE '241 PATENT)

36. Hospira realleges and incorporates by reference the allegations contained in paragraphs 1-35 of the Counterclaims as if set forth here.

Novartis incorporates by reference each of its answers to Paragraphs 1-35 above as if fully set forth herein.

37. The manufacture, use, sale, offer for sale, or importation into the U.S. of Hospira's proposed zoledronic acid products that are the subject of ANDA No. 202837 would not infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '241 patent.

Denied.

38. Hospira is entitled to a judicial declaration that its proposed zoledronic acid products that are the subject of ANDA No. 202837 would not infringe any valid and/or enforceable claim of the '241 patent.

Denied.

COUNTERCLAIM IV
(DECLARATION OF NON-INFRINGEMENT OF THE '987 PATENT)

39. Hospira realleges and incorporates by reference the allegations contained in paragraphs 1-37 of the Counterclaims as if set forth here.

Novartis incorporates by reference each of its answers to Paragraphs 1-38 above as if fully set forth herein.

40. The manufacture, use, sale, offer for sale, or importation into the U.S. of Hospira's proposed zoledronic acid products that are the subject of ANDA No. 202837 would not infringe, induce infringement of, or contribute to the infringement of, any valid and enforceable claim of the '987 patent.

Denied.

41. Hospira is entitled to a judicial declaration that its proposed zoledronic acid products that are the subject of ANDA No. 202837 would not infringe any valid and/or enforceable claim of the '987 patent.

Denied.

ANSWER TO HOSPIRA'S PRAYER FOR RELIEF

Novartis denies that Hospira is entitled to the relief it seeks in Paragraphs (A) – (F), or any other relief with respect to allegations made in the Counterclaims.

DATED: May 13, 2013

s/ William J. O'Shaughnessy
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CERTIFICATE OF SERVICE

I hereby certify that all counsel of record are being served via electronic mail and/or the ECF system with a copy of the foregoing **NOVARTIS'S ANSWER TO THE COUNTERCLAIMS OF HOSPIRA, INC.** on May 13, 2013.

DATED: May 13, 2013

s/ William J. O'Shaughnessy
William J. O'Shaughnessy